

EPA Registration No. 72977-3
Volume No. 2

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 72977-3

Send to SIG: check box ☐

This material is:

€ New stamped-accepted label

€ New CSF

€ Notification

€ Final Printed Label

* Other: File

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be **NO STAPLES** in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Jenkins

Phone: 308-6230 Division: AD

Date: 11/27/06



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 31 2006

Step toe & Johnson, LLP, Agent for
ETI H2O
c/o 1330 Connecticut Ave., N.W.
Washington, D.C. 20036-1795

Attention: Elizabeth Ann Brown, Ph.D.

Subject: Axen30
EPA Registration No. 72977-3
Amendment Application Date: October 13, 2006
EPA Received Date: October 13, 2006

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the material, the following comments apply.

- Add the following optional marketing statements are acceptable:

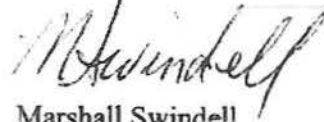
Trucks, Trailers, Shipping Containers, Rail Cars, Freight Line, Janitorial Line,
Janitorial Disinfectant, Janitorial and Silver Ion Formula

The proposed optional marketing statement, "Earth Choice"
is not acceptable. It is considered false and misleading.

This application has been made a part of the records of this file.

If you have any question or comments concerning this letter, please contact me at (703) 308 6341 or Portia Jenkins at (703) 308-6230.

Sincerely,

A handwritten signature in cursive script, appearing to read "M. Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510C)

WRITER'S DIRECT DIAL
202.419.5166

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
Tel 202.429.3000
Fax 202.429.3902
steptoe.com

October 13, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Marshall Swindell (PM 33)

Subject: Axen30, EPA Reg. No. 72977-3
Notification of other labeling revisions per PR Notice 98-10

Dear Marshall:

Attached please find a notification consistent with PR 98-10 for the above referenced label to include optional marketing statements.

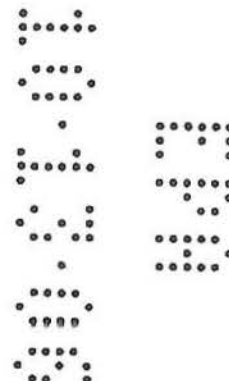
Please let me know immediately if there are any problems or concerns. Enclosed with this letter, please find EPA Form 8570-1 (including the certification statement) and one copy of the product labeling with each change highlighted.

Sincerely,

Elizabeth Anne Brown

Elizabeth Anne Brown, Ph.D.
Technical and Regulatory Analyst
ebrown@steptoe.com

cc: Ms. Dolana Blount, ETI H2O



	United States	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
	Environmental Protection Agency		
	Washington, DC 20460		

Application for Pesticide - Section I

1. Company/Product Number 72977-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Axen 30	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) ETI H2O 1725 Gillespie Way El Cajon, CA 92020	5. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)


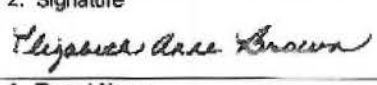
Notification of Other Labeling Revisions, per PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4-32 oz; 1-275 gallon		5. Location of label directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Elizabeth Anne Brown	Title Steptoe & Johnson, LLP Authorized agent	Telephone No. (Include Area Code) 202-419-5166
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received 
2. Signature 	3. Title Steptoe & Johnson, LLP Authorized Agent	
4. Typed Name Elizabeth Anne Brown	5. Date October 13, 2006	

Axen® 30

Disinfectant, Fungicide & Virucide*

[Disinfects and Deodorizes]
[Restaurants] • [Hospitals] • [Schools] • [Homes] •
[Offices] • [Trucks] • [Trailers] • [Shipping Containers]
• [Rail Cars]

Manufactured by ETI H2O
A Division of Innovative Medical
Services
1725 Gillespie Way
El Cajon, CA 92020
EPA REG. No. 72977-3
EPA EST. No. 72977-CA-001

Active Ingredient

Silver† 0.003%
Citric Acid 4.840%

Other Ingredients 95.157%

Total 100.000%

† Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

NOTE: Bracketed information is optional wording for product specific labels

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*. **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** should be used on non-porous environmental hard surfaces in [homes], [hospitals], [nursing] [homes], [medical and dental clinics], [laboratories], [ambulance and patient transfer vehicles], [funeral homes], [hotels], [restaurants], [schools], [day care facilities], [offices], [veterinary clinics], [animal shelters], [kennels], [exercise facilities], [beauty and barber shops], [trucks], [trailers], [shipping containers], [rail cars], [subways], [trains], [airplanes], [ships], [busses] and [other public transportation vehicles], [locker rooms], [kitchens] and [restrooms].

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray has been formulated to disinfect hard, non-porous environmental surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects including [walls], [floors], [counters], [sinks], [exterior toilet surfaces], [cabinets], [tubs], [showers], [doorknobs], [lights switch covers], [telephones], [appliances], [stove tops], [bed frames], [wheelchairs], [over-bed tables], [examination tables] and [waste containers], [tables], and [chairs].

[This product] can be used in [homes], [schools], [nurseries], [daycare centers], [playrooms], [playground and/or recreational facilities], [washrooms], [kitchens], [restrooms and/or bathrooms], [school buses].

Use to disinfect the following hard, non-porous surfaces: [children's toys], [toys] [toy box(s)], [diaper pail(s)], [diaper changing table(s)], [bathroom and/or kitchen counter(s)], [desk(s)], [play table(s)], [computer keyboard], [telephone] [doorknob(s)], [jungle gym(s)], [playhouse(s)], [child car seat], [stroller(s)], [crib(s)], [playpen(s)], [activity center(s)], [tanning beds];

[FAST], [EASY], [EFFECTIVE]
General Information

AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray successfully killed the following organisms under AOAC protocols (in order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

Organism	Kill Time
† <i>Pseudomonas aeruginosa</i> ¹	30 seconds
† <i>Staphylococcus aureus</i> ¹	30 seconds
† <i>Salmonella choleraesuis</i> ¹	30 seconds
† <i>Listeria monocytogenes</i> ¹	30 seconds
Vancomycin resistant <i>Enterococcus faecium</i> ¹	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> ¹	2 minutes
<i>Escherichia coli</i> 0157:H7 ¹	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	10 minutes
†*HIV type 1- Strain HTLV IIIB ¹	30 seconds
*Herpes Simplex Type 1 VR-733 F(1) Strain ²	1 minute
*Influenza A VR-544, Hong Kong strain ²	10 minutes
*Rhinovirus R37 VR-1147, Strain 151-1 ²	10 minutes
*Polio Type 2, VR-1002, Lansing Strain ²	10 minutes

[1 Evaluated in the presence of 5% organic soil.]

[2 Evaluated in the presence of 1% organic soil]

[Fungicidal Activity: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus. Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.]

[Deodorizes: AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.]

APPLICATION INSTRUCTIONS

Pre-clean surfaces prior to using this product.

General Disinfection:

For general disinfection and control of the bacteria *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Listeria monocytogenes*, Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* 0157:H7 the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, **AXEN® 30™ Disinfectant, Fungicidal & Virucidal Spray** provides protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* up to 24 hours after initial application.

Fungus Control:

For effective control of the fungus *Trichophyton mentagrophytes*, the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

*Viral Control:

To kill Herpes Simplex Type 1 F(1) Strain Influenza A Virus, Hong Kong strain, Rhinovirus R37 Strain 151-1, Polio Virus Type 2 Lansing Strain the surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 10 minutes. The surface may then be wiped dry with a clean towel.

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV); **Instructions for Cleaning and Decontamination Against HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids:** **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** to area to be treated. The surface must be completely wet with **AXEN® 30 Disinfectant, Fungicidal & Virucidal Spray** for 30 seconds. The surface may then be wiped dry with a clean towel. This contact time will not control all organisms listed on this label. Refer to application instructions for other organisms. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

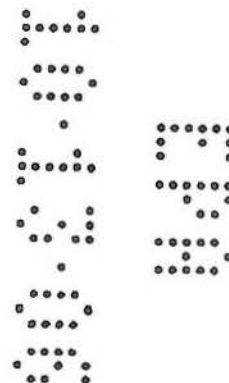
This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not normally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Storage:	Do not contaminate water, food or feed by storage or disposal.
Disposal:	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.

IN CASE OF EMERGENCY

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.



Additional language for front or back panel

Kills *Staphylococcus aureus* in 30 seconds†

Kills *Salmonella choleraesuis* in 30 seconds†

Kills *Listeria monocytogenes* in 30 seconds†

Kills *Pseudomonas aeruginosa* in 30 seconds†

Kills germs in 30 seconds†

Kills common household germs

Kills common household germs including *Salmonella*, *Staphylococcus*, *Listeria*, and *E. coli*.

Kills [*Salmonella*], [*Staphylococcus*], [*Listeria*], and [*E. coli*].

Kills - Bacteria, Fungus and Virus*

[Kills] [Eliminates] MRSA

[Kills] [Eliminates] Methicillin Resistant Staph

[Kills] [Eliminates] Methicillin Resistant *Staphylococcus aureus*

[Kills] [Eliminates] VRE

[Kills] [Eliminates] Vancomycin-resistant Enterococcus

[Kills] [Eliminates] Vancomycin resistant Enterococcus faecium

[Kills] [Eliminates] HIV

[Kills] [Eliminates] Herpes Simplex Virus

[Kills] [Eliminates] Influenza A Virus

[Kills] [Eliminates] Rhinovirus

[Kills] [Eliminates] Polio Virus Type

Silver [Ion] Formula

No dulling residue

Disinfects without bleaching

No harsh chemical smell

Odorless

Disinfects household surfaces

No Mixing Required

Powered by [Axenohl®] [SDC 2400] [Axenohl Alternate brand name]

For daily use

Patented formula

Use for a [fresh] [home] [environment] [kitchen]

Commercial Line

Industrial Line

Hospital Line

Consumer Line

Retail Line

Freight Line

Janitorial Line

Janitorial Disinfectant

Odoban® [Commercial], [Janitorial], [Earth Choice] (use restricted to the trademark owner)

KEY:

*= Refer to viruses

†= Refer to organisms controlled with 30 second kill time



Alternate language for the front or back panel

[Formulated for] [Hospitality Environment] [Institutional] [Childcare
Environments] [Medical & Nursing Environment]

**Optional graphics for back of label (graphics are larger here than they will
appear on the label)**



DECISION PKG. NO.

37552

SUBM. DUE DATE

11/12/06

SUBMISSION BAR CODE #

800546

REVIEWER

PJ

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO.

72977-3

PM

33

ACTION CODE

332

DESCRIPTOR

FQPA & NFQPA

☐ CHILD RESISTANT PACKAGING:☐ REQUIRED☐ NOT REQUIRED

REGISTRATION TYPE:

☐ CONDITIONAL☐ UNCONDITIONAL☐ RESTRICTED USE

DATE ON APPLICATION

10, 13, 06

EPA RECEIVE DATE

10, 13, 06

PM RECEIVE DATE

10, 16, 06

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL ☐ SELECTIVE☐ NOT SUBMITTED ☐ N/A☐ SUBMITTED ☐ NOT SUBMITTED☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNEDCHEMISTRY ☐ ☐ ☐ ☐EFFICACY ☐ ☐ ☐ ☐ACUTE TOX. ☐ ☐ ☐ ☐RASSB TOX. ☐ ☐ ☐ ☐ENVIRON. PATE ☐ ☐ ☐ ☐FISH/WILDLIFE ☐ ☐ ☐ ☐OTHER: : ☐ ☐ ☐ ☐

STATUS

RESPONSE CODE

RESPONSE DATE

SCIENCE
GROUP

DIVISION

BRANCH

SECTION

CSF
Y/NLABEL
Y/N

CHEMISTRY AD EASSB CTT

EFFICACY AD EASSB EET